

Serial No. 09/589,510
Group Art Unit: 1638

REMARKS

Reconsideration of the present application is respectfully requested. Claims 1, 3-9 and 14-28 are pending. Claims 1, 17, 21, and 27 have been amended. Applicants reserve the right to pursue this claim in a continuing application. Support for the amendments is found in the claims as originally filed, and throughout the specification. No new matter has been added.

Rejections under 35 U.S.C. §112, 1st Paragraph - New Matter:

Claims 1, 3-9, 14, 17-18, and 20-28 are rejected under 35 U.S.C. §112, first paragraph as containing subject matter which was not described in the specification in such a way to reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention.

The Examiner asserts that the phrase "polypeptide having helicase activity" has no basis in the specification or in the claims as originally filed.

Applicant respectfully disagrees. In *Fujikawa v. Wattanasin* (93 F.3d 1559, 39 USPQ2d 1895, Fed. Cir. 1996) the court pointed out "[l]apsis verbis disclosure is not necessary to satisfy the written description requirement of section 112". As the Examiner points out, "helicase" is recited on page 2 of the specification where the specification discusses RuvB and describes functional motifs common to DNA helicases. Page 2, lines 17-19 of the specification states, "Two hexameric RuvB units bind to DNA in a symmetrical manner to form a ring, similar to the hexameric ring formed by *other* DNA helicases" (emphasis added), which clearly indicates RuvB is a polypeptide having helicase activity. This disclosure is sufficient to support the phrase "polypeptide having helicase activity." However, in order to expedite prosecution, claims 1 and 17 have been amended as per the Examiner's recommendation and now recite a "polypeptide having RuvB activity". Therefore the rejection of claims 1, 3-9, 14, 17-18, and 20-28 under 35 U.S.C. §112, first paragraph is obviated and should be withdrawn.

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Claim 21 is also rejected under 35 U.S.C. §112, first paragraph for containing subject matter not described in the specification.

The Examiner asserts that "non-human" has no basis in the specification or in the claims as originally filed.

Claim 21 has been amended to delete the term "non-human", therefore the rejection is obviated.

Applicants have properly addressed by argument and amendment the grounds for the rejection of claims 1, 3-9, 14, 17-18, and 20-28 under 35 U.S.C. §112, first paragraph and respectfully request that the rejection be withdrawn.

Rejections under 35 U.S.C. §112, 2nd Paragraph:

Claims 1, 3-9, 14, 17-18, and 20-27 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite.

The Examiner asserts that the term "member" renders claims 1 and 17, and dependent claims 3-9, 18, and 20-26 indefinite. The Examiner points out that claim 27 is indefinite for depending on claim 45.

The Applicant respectfully disagrees that recitation of a "member selected from the group" in the preamble makes claims 1 and 17 indefinite since this is common Markush group claim format and parts (a) and (b) of the claims clearly recite a "nucleic acid sequence". However, in order to expedite prosecution, claims 1 and 17 have been amended to replace the term "member" with the term "nucleic acid sequence". Therefore, the rejection of claims 1 and 17, as well as dependent claims 3-9, 18, and 20-26 under 35 U.S.C. §112, second paragraph is obviated.

Claim 27 has been amended to correct a clerical error, and is now dependent on claim 23. Applicant thanks the Examiner for pointing out this error. The amendment to claim 27 obviates the rejection of claim 27 under 35 U.S.C. §112, second paragraph.

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Applicants have properly addressed by argument and amendment the grounds for the rejection of claims 1, 3-9, 14, 17-18, and 20-27 under 35 U.S.C. §112, second paragraph and respectfully request that the rejection be withdrawn.

Rejections under 35 U.S.C. §112, 1st Paragraph, Enablement:

Claims 1, 3-9, 14, 16-18, and 20-28 are rejected under 35 U.S.C. §112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The Examiner asserts that the specification does not provide enablement for any isolated polynucleotide having at least 90% or 95% sequence identity to SEQ ID NO: 3. The Examiner asserts that the Applicant must show a sequence having 90% sequence identity to SEQ ID NO: 3 that encodes a polypeptide with helicase activity in order to enable the claims. The Examiner asserts that the Applicant must show a polynucleotide comprising any 100 contiguous bases of SEQ ID NO: 3, or encodes any 50 contiguous amino acids of SEQ ID NO: 4 and retains activity.

Applicants respectfully disagree, it is respectfully submitted that 35 U.S.C. §112 does not require a working example. Further, case law does not require that an application provide a working example. It is only required that the application teach the person skilled in the art how to make and use the invention. The present application meets that requirement. The Examiner has restricted prosecution to one polynucleotide sequence, but Applicants disclose five polynucleotide sequences, each of which encode a full-length polypeptide having overall homology to known RuvB sequences and further containing conserved motifs seen in the known RuvB sequences (see Example 4 page 62-63, and Appendix A submitted in response filed 2/19/02). For example, Applicants submit in Appendix B a GAP alignment of elected sequence SEQ ID NO: 3 with the other polynucleotide sequences of the invention which shows that SEQ ID NO: 3 has from 87.2% - 97.6% sequence identity to SEQ ID NOS: 1, 5, 7, and 9. Even though it is not required for enablement, Applicants

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have shown other isolated sequences having about 90% or 95% sequence identity to SEQ ID NO: 3, and that comprise 100 contiguous nucleotides of SEQ ID NO:3, or encode 50 contiguous amino acids of SEQ ID NO: 4, therefore the rejection should be withdrawn.

The Examiner asserts that the state of the prior art teaches that structural identity between two DNA/protein sequences does not necessarily mean that the sequences have the same function. The Examiner cites Lazar *et al.* (MCB 1988 8(3):1247-1257) and Broun *et al.* (Science 1998 282:131-133) which each provide examples of very specific limited amino acid changes which resulted in elimination or alteration of the experimental protein's catalytic activity. The Examiner also states "Applicants note the nucleic acid sequences encoding the proteins disclosed by Lazar or Broun would share at least 90% or 95% sequence identity to SEQ ID NO: 3".

Applicants respectfully disagree. The nucleic acid sequences encoding the proteins disclosed by Lazar or Broun would not share 90% or 95% sequence identity to SEQ ID NO: 3, Lazar discloses modifications to a human transforming growth factor α (TGF α) sequence, Broun discloses modifications to a oleate 12-desaturase sequence. Neither discloses any RuvB sequences or modifications thereto that would share 90% or 95% sequence identity to SEQ ID NO: 3. Applicant notes that Lazar states "When aspartic acid 47 was mutated to alanine or asparagine, biological activity was retained..." (page 1247, Abstract), so Lazar demonstrates that not all substitutions, including non-conservative ones as noted above, impact the biological activity of a protein. Broun *et al.* actually note the high sequence similarity between the oleate 12-desaturase and oleate hydroxylase and use this to identify seven residues conserved in desaturases and to target them for modification and activity (see page 131, column 2 – column 3). Broun *et al.* actually use the sequence similarity of the desaturase and the hydroxylase to predict which residues to change to alter the activity of the desaturase. Similarly, the disclosure of SEQ ID NOS: 1-10, the conserved domains and motifs shown in Example 4 and known in

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the art, the sequence identity and similarity to other known RuvB sequences (for example, pages 1-3, and Appendix A submitted 2/19/02), the guidance on sequence analyses, comparison, and identity (for example, page 16, line 28 – page 22, line 2; and Example 3), the guidance on codon degeneracy, silent variants, and preferences (page 6, lines 10-26; page 7, line 18 – page 8, line 3), the guidance on conservative amino acid substitutions (page 6, line 27 – page 7, line 16), the guidance on nucleic acid isolation and evaluation (page 13, line 30 – page 14, line 3; page 14, line 24 – page 16, line 11; page 25, line 10 – page 27, line 27; page 32, line 6 – page 37, line 34; and Examples 1 and 2) and the ready availability in the art for assays for RuvB (see Response After Final filed 8/14/02) show the specification coupled with the knowledge in the art enables a person in the art to make and use sequences having 90% or 95% sequence identity to SEQ ID NO: 3 having RuvB/helicase activity.

The Examiner cites Amgen Inc. Chugai Pharmaceutical Co. Ltd., 18 USPQ 2d 1016 at 1021 and 1027 (Fed. Cir. 1991). At page 1021 it is taught that a gene is not reduced to practice until the inventor can define it by its "physical or chemical properties" and at page 1027 it is taught that the disclosure of a few sequences did not enable claims broadly drawn to any analog thereof.

In *Amgen v. Chugai*, the Federal Circuit concluded that the patent specification was insufficient to enable one of ordinary skill in the art to make and use the invention claimed in claim 7 of the '008 patent without undue experimentation. As stated on page 1027, however, "it is not necessary that a patent applicant test all the embodiments of his invention, *In re Angstadt*, 537 F.2d 498, 502, 190 USPQ 214, 218 (CCPA 1976); what is necessary is that he provide a disclosure sufficient to enable one skilled in the art to carry out the invention commensurate with the scope of his claims. For DNA sequences, that means disclosing how to make and use enough sequences to justify grant of the claims sought." Applicants respectfully submit, that has been done in the instant

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specification. The present invention discloses how to make and use the sequences of the invention, as discussed in the paragraph above.

The question of experimentation is a matter of degree. The fact that some experimentation is necessary does not preclude enablement; what is required is the amount of experimentation must not be unduly extensive. *PPG Inc. v. Guardian Industries Corp.* (37 USPQ 1218, 1623, (Fed. Cir. 1996). The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed. *Ex parte Jackson*, 217 USPQ 804, 807 (1982 PTOBA).

With the guidance provided in the present specification, one skilled in the art can readily practice the claimed invention. Therefore, it is respectfully requested that the rejection of claims 1, 3-9, 14, 16-18, and 20-28 under 35 U.S.C. §112, first paragraph be withdrawn.

Rejections under 35 U.S.C. §112, 1st Paragraph, Written Description:

Claims 1, 3-9, 14, 17-18 and 20-28 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter not sufficiently described in the specification to indicate the inventor(s) had possession of the invention.

The Examiner asserts that the Applicant has only described the isolated polynucleotide encoding SEQ ID NO: 4. The Examiner also states that since the Applicant has not described a single species of a polynucleotide having 90% or 95% sequence identity to the disclosed sequences and encoding a polypeptide having helicase activity, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that one skilled in the art would recognize that Applicants are in possession of the invention as broadly claimed. The Examiner asserts the Applicants must show a sequence having 90% sequence

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identity to SEQ ID NO: 3 that encodes a polypeptide with helicase activity in order to show possession of the invention as claimed.

The Examiner is reminded that every species encompassed by the claimed invention need not be disclosed in the specification to satisfy the written description requirement of 35 U.S.C. § 112, first paragraph. *Utter v. Hiraga*, 845 F.2d 993, 6 USPQ2d 1709 (Fed. Cir. 1988). In fact, the description of a claimed genus can be by structure, formula, chemical name, or physical properties. See *Ex parte Maizel*, 27 USPQ2d 1662, 1669 (B.P.A.I.1992), (citing *Amgen v. Chugai*, 927 F.2d 1200, 1206 (Fed. Cir. 1991)).

Claims 1 and 17 recite that the sequence shares 90% sequence identity to the sequence of SEQ ID NO: 3 or SEQ ID NO: 4, respectively. The recitation of at least 90% sequence identity, is a very predictable structure of the sequences encompassed by the claimed invention. Further, as noted above, Applicants have provided other isolated sequences comprising 87.2% - 97.6% sequence identity to SEQ ID NO: 3. The description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces. 66 Fed. Reg. 1099, 1106 (2000). Satisfactory disclosure of a "representative number" depends on whether one of skill in the art would recognize that the Applicants were in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. 66 Fed. Reg. 1099, 1106 (2000). Applicants submit that the knowledge and level of skill in the art would allow a person of ordinary skill to envision the claimed invention, *i.e.*, a sequence having at least 90% sequence identity to the sequence set forth in SEQ ID NO: 3.

A genus of DNAs may be described by means of a recitation of a representative number of DNAs, defined by nucleotide sequence, falling within the scope of the genus, or by means of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1569 (Fed. Cir. 1997); see

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also Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, first paragraph, "Written Description" Requirement, 66 Fed. Reg. 1099, 1106 (2000). The recitation of a predictable structure of at least 90% sequence identity to SEQ ID NO: 3 is sufficient to satisfy the written description requirement.

In addition, an Applicant may rely upon functional characteristics in the description, provided there is a correlation between the function and structure of the claimed invention. *Id.*, citing *Lilly* at 1568. Claims 1 and 17 recite that the claimed sequences are, or encode, a polypeptide having helicase (RuvB) activity thereby providing a functional characterization of the sequences claimed in the genus.

Example 14 of the Revised Interim Written Description Guidelines is directed to a generic claim: a protein having at least 95% sequence identity to the sequence of SEQ ID NO:3, wherein the sequence catalyzes the reaction $A \rightarrow B$. The Training Materials concludes that the generic claim of Example 14 is sufficiently described under § 112, first paragraph, because 1) "the single sequence disclosed in SEQ ID NO:3 is representative of the genus" and 2) the claim recites a limitation requiring the compound to catalyze the reaction from $A \rightarrow B$. The Guidelines conclude that one of skill in art would recognize that the Applicants were in possession of the necessary common attributes possessed by the members of the genus.

Following the analysis of Example 14, Applicants submit that claims 1 and 17 satisfy the written description requirements of § 112, first paragraph. Specifically, the claims of the present invention encompass sequences having at least 90% sequence identity to the sequence of SEQ ID NO: 3 or 4, wherein the claimed sequences encode a polypeptide having helicase (RuvB) activity. As in Example 14, the specification discloses the nucleic acid sequence of SEQ ID NO: 3, and the amended claims recite a limitation requiring the sequence to have a specific function.

Consequently, contrary to the Examiner's conclusion, the sequences encompassed by the genus of claims 1 and 17 are defined by relevant identifying physical and chemical properties. In fact, the common attributes or features of the

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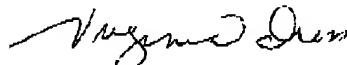
elements possessed by the members of the genus is that they are RuvB sequences and share at least 90% sequence identity at the nucleotide level to the disclosed nucleotide sequence of SEQ ID NO: 3. The necessary common features of the claimed genus are clear.

Applicants have disclosed five isolated polynucleotide sequences and the encoded RuvB polypeptides in SEQ ID NOS: 1-10, and have provided further guidance on sequence isolation, analysis, and identification, codon degeneracy, conserved protein domains and motifs, as well as conservative amino acid substitutions. Applicants clearly had possession of sequences having 90% or 95% sequence identity to SEQ ID NO: 3 or 4, therefore the rejection of claims 1, 3-9, 14, 17-18 and 20-28 are rejected under 35 U.S.C. §112, first paragraph written description should be withdrawn.

CONCLUSION

In light of the foregoing remarks and amendments, it is believed that claims 1, 3-9 and 14-28 are in condition for allowance. Withdrawal of the outstanding rejections and allowance of all of the remaining claims is respectfully requested.

Respectfully submitted,



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APPENDIX B

GAP of: 1121SID1 check: 5036 from: 1 to: 1845

WPDEF Case 1121 SEQ ID NO: 1 RuvB

Case 1121 SEQ ID NO: 1. RuvB. Imported via clipboard 11/5/01

to: 1121SID3 check: 4044 from: 1 to: 1912

WPDEF Case 1121 SEQ ID NO: 3 RuvB

Case 1121 SEQ ID NO: 3. RuvB. Imported via clipboard 11/5/01

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WPDEF Case 1121 SEQ ID NO: 3 RuvB

Case 1121 SEQ ID NO: 3. RuvB. Imported via clipboard 11/5/01

to: 1121SID5 check: 5768 from: 1 to: 1886

WPDEF Case 1121 SEQ ID NO: 5 RuvB

Case 1121 SEQ ID NO: 5 RuvB. Imported via clipboard 11/5/01.

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November 5, 2001 17:01 ..

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GAP of: 1121SID3 check: 4044 from: 1 to: 1912

WPDEF Case 1121 SEQ ID NO: 3 RuvB

Case 1121 SEQ ID NO: 3. RuvB. Imported via clipboard 11/5/01

to: 1121SID7 check: 5890 from: 1 to: 1898

WPDEF Case 1121 SEQ ID NO: 7 RuvB

Case 1121 SEQ ID NO: 7 RuvB. Imported via clipboard 11/5/01

Symbol comparison table: /app/gcg/10.1/gcgcore/data/rundata/nwsgapdna.cmp

CompCheck: 8760

Gap Weight:	50	Average Match:	10.000
Length Weight:	3	Average Mismatch:	0.000

Quality:	15405	Length:	2009
Ratio:	8.116	Gaps:	11
Percent Similarity:	89.173	Percent Identity:	89.117

Match display thresholds for the alignment(s):

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1121SID3 x 1121SID7 November 5, 2001 17:01 ..

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1605 tgcctgtgtgtgtttttatcttgcctcatcggtgtccgggaatctgtgcttc 1654
1748 caccgggtgtattggcccgaaacctatctttgtaaccatggataatggat 1797
|||||

1655 cacgggttgattggccgaaccctatctttgtaaccatggataatggat 1704
1798 aggattcttacagaatgcaacttgcattggctttattatttctaaatgtcc 1847
|| |||||
1705 agcattcttacagaatgcaacttgcattggctttattatttctaaatgtcc 1754
1848 ataaagcataacgaaatgtttctacaacmtwtaaaaaaaaaaaaaaaaaaaa 1897
||||| ||||| |||||:|:| |||
1755 ataaagcttaacaaatgtttctacaacatatagacctcctgcocaaatt 1804
1898 aaaaaaaaaaaaaa..... 1912
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1805 aaaattcgttttagcttagataattaatgggtacatacactactttatgt 1854
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